7.2 Clinical and Epidemiologic Studies

Described below are examples of the types of activities in which the collaboration may engage, subject to the mutually agreed upon priorities above, the financial resources available, and the requirements for prior approval by the Executive Committee (see 6.2) and Ethical Review Board and CDC IRB (6.4).

7.2.1 Study Goals

Studies may be implemented to:

+ Delineate the clinical course and response to treatment of HIV infection.

+ Determine the clinical spectrum of opportunistic diseases and conditions affecting infected persons.

+ Develop, implement, and evaluate the efficacy of various interventions to control the spread or impact of HIV infection, including health education measures, community outreach programs, mass media advertising, and new vaccines, virucides, prophylaxes or treatment for HIV, other sexually transmitted infections, tuberculosis, or other related opportunistic conditions.

7.2.2 Potential Study Subjects

+ intravenous drug users,
+ commercial sex workers,
+ prisoners,
+ patients at sexually-transmitted disease clinics,
+ spouses and sexual partners of persons with HIV infection or at risk for same,
+ hemophiliacs and other blood transfusion recipients
+ other groups at high-risk for HIV infection,
+ women seeking prenatal care,
+ newborn infants,
+ hospital patients,
+ blood donors,
+ healthy controls for comparison purposes,
+ other sentinel low-risk groups presumed to be representative of the general population,
+ sex partners or contacts of the above,
+ persons with potential opportunistic diseases, such as

leprosy or tuberculosis,
+ members of the general population for developing health education strategies.

7.2.3 Types of studies

+ Surveys collecting questionnaire information and/or blood or other body fluids and tissues,
+ case-control studies,
+ retrospective studies,
+ cross-sectional studies,
+ cohort/prospective studies,
+ focus groups and other non-quantitative studies.
+ clinical trials

7.3 Laboratory Investigations

The collaboration may perform serologic and virologic testing to detect antibody, antigen, viral DNA or other markers of HIV or similar agents, or to isolate virus in order to support the clinical and epidemiological studies of the collaboration, and may do so in conjunction with qualified collaborators. Related laboratory work may be carried out to support the clinical and epidemiological studies of the collaboration, e.g., collection and quantitative typing of lymphocytes or immunoglobulins. If included in specific protocols receiving the advance approval (Section 5.2) of the Executive Committee (Section 6.2), some laboratory testing may occur in collaborating research labs outside of Thailand, such as at CDC-Atlanta or elsewhere.

7.4 Training

7.4.1 The collaboration may assist in identifying, facilitating, arranging and/or providing short-term or long-term training in the U.S. and in Thailand for public health and medical personnel who will serve as a nucleus to develop and disseminate a system and network of training programs for other health workers in Thailand and internationally.

7.4.2 The focus of such training may include:

+ Epidemiological methods and skills for surveillance, monitoring, and study of the HIV and AIDS epidemics,

+ Laboratory methods and procedures related to the diagnosis

or detection of HIV infection or the measurement of immunological function, including quality control of laboratory testing.

+ Clinical management of patients with HIV infection and various opportunistic diseases,

+ Intervention and prevention modalities for personnel responsible for control efforts,

+ Policy and content for the development of programs to counsel persons before and after HIV-testing,

+ Policy-making for setting national guidelines for medical care and public health response to the HIV and AIDS epidemics.

7.4.3 The amount and frequency of such training is dependent on the financial and personnel resources which may be available to the collaboration, and no specific quantity of such training is intended by this collaboration.

7.5 Consultation and Assistance

Collaboration staff may teach, lecture, facilitate, consult with, or help arrange outside assistance for collaborating Thai institutions in areas of epidemiology, laboratory science, surveillance, monitoring, patient management, education, policy, research, or prevention and control of HIV/AIDS, STD and TB. Such activities are dependent on available financial and personnel resources.

7.6 Changes in the scope-of-work

Changes in the scope-of-work of this collaboration shall require the advance mutual consent of the Parties.

8. RESPONSIBILITIES AND OBLIGATIONS OF THE PARTIES

8.1 All activities and obligations under this Agreement are subject to the availability of appropriated funds.

8.2 CDC Responsibilities and Obligations

8.2.1 CDC Financial Commitments

- Salaries and prescribed benefits for official U.S. Government employees and local hire staff;
- Purchase and maintenance of furniture, supplies, equipment, and reagents for collaboration offices, laboratories and studies;
- Purchase of vehicles, fuel, maintenance and repairs for same;
- Usage charges for telephone and other telecommunication services, such as telex and international computer message and data transmission services;
- Authorized transportation and shipping expenses required for collaboration activities;
- Authorized travel and miscellaneous incidental and associated expenses of the collaboration;
- Incidental reimbursement and compensation (See 6.12)
- Usage charges for electricity consumption by collaboration offices and laboratories, including use of scientific equipment, office equipment, and air conditioning, plus other normal utilities;

8.2.2 CDC LONG-TERM STAFFING Commitments:

Subject to the appropriation of funds, CDC will provide at least two U.S. staff for long-term assignment to the collaboration in accordance with the nomination procedures and approvals in Section 6.7.

8.2.3 CDC SHORT-TERM STAFFING commitments:

CDC will also provide, on an as-needed basis within the limits of available resources, additional official U.S. Government employees for short-term assignments to assist on collaboration activities and needs.

8.2.4 CDC ADMINISTRATIVE SERVICES commitments:

+ Procurement and shipment to Thailand of specialized supplies, equipment and reagents for the collaboration.

+ Personnel actions and administrative support for U.S. Government CDC employees assigned to the collaboration.

8.3 ROYAL THAI GOVERNMENT Responsibilities and Obligations

8.3.1 RTG FINANCIAL commitments:

+ Salaries and prescribed benefits of RTG employees assigned on detail as RTG staff of the collaboration.

+ Waste and garbage collection and sewage disposal from collaboration offices and laboratories;

8.3.2 RTG STAFFING commitments:

The RTG may provide, in accordance with 6.8 and 6.9 RTG staff for long term assignment with the collaboration.

8.3.3 RTG SPACE commitments:

The RTG shall be responsible to identify and provide both office and laboratory and parking space that is deemed suitable for the collaboration.

Suitability of the space shall be determined by its:

+ size,
+ location and contiguity,
+ access to Thai institutions responsible for care of AIDS patients,
+ type of construction and capability to meet laboratory and office requirements,
+ security from unauthorized entry or theft,
+ sufficiency of parking spaces reserved for collaboration and staff vehicles.

9. DURATION AND CHANGES TO THE COLLABORATION

All activities undertaken pursuant to this Agreement will be

subject to the laws and regulations of the United States of America and the Royal Thai Government. This collaboration enters into force upon signature for a period of five years, effective August 8, 1999. It may be terminated earlier by either party upon written notice to the other at least 6 months in advance of the proposed date of termination. This collaboration may be amended or extended by written consent of the Parties.

This collaboration is agreed to by the Parties upon the signatures below of their authorized representatives.

FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION, UNITED STATES PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Signature: Date:

Stephen B. Blount MD 10/21/99

Name: Stephen B. Blount, MD, MPH
Title: Associate Director for Global Health

FOR THE THAILAND MINISTRY OF PUBLIC HEALTH

Signature: Date:

S. Sriprapandh 12 OCT 1999

Name: Dr. Sucharit Sriprapandh
Title: Permanent Secretary

Signature: Date:

Name:
Title:

ANNEX I

The following terms and titles are used in this document:

"Affiliated staff"	- Persons approved to work on collaboration activities as employees of other agencies cooperating with the collaboration on specific research studies or activities.
"AIDS"	- Acquired immunodeficiency syndrome.
"CDC"	- Centers for Disease Control and Prevention, Atlanta, U.S. Department of Health and Human Services.
"HIV"	- Human immunodeficiency virus.
"Local hire staff"	- Independent employees employed for the collaboration.
"MOPH"	- Ministry of Public Health, Thailand
"RTG"	- Royal Thai Government of the Kingdom of Thailand
"RTG Staff"	- Royal Thai Government employees detailed to work full-time on the collaboration.
"STD"	- Sexually Transmitted Disease
"TB"	- Tuberculosis
"UNAIDS"	- Joint United Nations Programme on HIV/AIDS
"U.S. staff"	- Official U.S. Government CDC employees assigned to the collaboration.
"Voluntary staff"	- Persons approved to work on collaboration activities on a volunteer basis.
"WHO"	- World Health Organization

ANNEX II

INTELLECTUAL PROPERTY

Pursuant to Paragraph 5.5 of this Agreement:

The Parties shall ensure adequate and effective protection of intellectual property created or furnished under this Agreement and relevant implementing arrangements. The Parties agree to notify one another in a timely fashion of any inventions or copyrighted works arising under this Agreement and to seek protection for such intellectual property in a timely fashion.

Rights to such intellectual property shall be allocated as provided in this Annex.

I. SCOPE

A. This Annex is applicable to all cooperative activities undertaken pursuant to this Agreement, except as otherwise specifically agreed by the Parties or their designees.

B. For purposes of this Agreement, "intellectual property" shall have the meaning found in Article 2 of the Convention Establishing the World Intellectual Property Organization, done at Stockholm, July 14, 1967.

C. This Annex addresses the allocation of rights, interests, and royalties between the Parties. Each Party shall ensure that the other Party can obtain the rights to intellectual property allocated in accordance with the Annex, by obtaining those rights from its own participants through contracts or other legal means, if necessary. This Annex does not otherwise alter or prejudice the allocation between a Party and its nationals, which shall be determined by that Party's laws and practices.

D. Disputes concerning intellectual property arising under this Agreement should be resolved through discussions between the concerned participating institutions or, if necessary, the Parties or their designees. Upon mutual agreement of the Parties, a dispute shall be submitted to an arbitral tribunal for binding arbitration in accordance with the applicable rules of international law. Unless the Parties or their designees agree otherwise in writing, the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL) shall govern.

E. Termination or expiration of this Agreement shall not affect rights or obligations under this Annex.

II. ALLOCATION OF RIGHTS

A. Each Party shall be entitled to a non-exclusive, irrevocable, royalty-free license in all countries to translate, reproduce, and publicly distribute scientific and technical journal articles, reports, and books directly arising from cooperation under this Agreement. All publicly distributed copies of a copyrighted work prepared under this provision shall indicate the names of the authors of the work unless an author explicitly declines to be named.

B. Rights to all forms of intellectual property, other than those rights described in Section II.A. above, shall be allocated as follows:

1. Visiting researchers, for example, scientists visiting primarily in furtherance of their education, shall receive intellectual property rights under the policies of the host institution. In addition, each visiting researcher named as an inventor shall be entitled to share in a portion of any royalties earned by the host institution from the licensing of such intellectual property.

2. (a) For intellectual property created during joint research, for example, when the Parties, participating institutions, or participating personnel have agreed in advance on the scope of work, each Party shall be entitled to obtain all rights and interests in its own territory. Rights and interests in third countries will be determined in implementing arrangements. If research is not designated as "joint research" in the relevant implementing arrangements, rights to intellectual property arising from the research will be allocated in accordance with paragraph II.B.(1). In addition, each person named as an inventor shall be entitled to share in a portion of any royalties earned by either institution from the licensing of the property.

(b) Notwithstanding paragraph II.B.2.(a), if a type of intellectual property is protected under the laws of one Party but not the other Party, the Party whose laws provide for this type of protection shall be entitled to all rights and interests worldwide. Persons named as inventors of the property shall nonetheless be entitled to royalties as provided in paragraph II.B.2.(a).

III. BUSINESS-CONFIDENTIAL INFORMATION

In the event that information identified in a timely fashion as business-confidential is furnished or created under the Agreement, each Party and its participants shall protect such information in accordance with applicable laws, regulations, and administration practice. Information may be identified as "business-confidential" if a person having the information may derive an economic benefit from it or may obtain a competitive advantage over those who do not have it, the information is not generally known or publicly available from other sources, and the owner has not previously made the information available without imposing in a timely manner an obligation to keep it confidential.

Both Parties agree that no information or equipment requiring protection in the interests of national defense or foreign relations of either Party and classified in accordance with the applicable national laws and regulations shall be provided under this Agreement. In the event that information or equipment which is known or believed to require such protection is identified in the course of cooperative activities undertaken pursuant to this Agreement, it shall be brought immediately to the attention of the appropriate officials and the Parties shall consult to identify appropriate security measures to be agreed upon by both Parties in writing and applied to this information and the equipment and shall, if appropriate, amend this Agreement to incorporate such measures.